UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

LASANDRA MADDEN AND LEVELL MADDEN, Individually, and on Behalf Of LABREA WILLIAMS, a minor child,

Plaintiffs,

v.

WYETH, d/b/a WYETH, INC., f/k/a AMERICAN HOME PRODUCTS CORPORATION; WYETH CONSUMER HEALTHCARE, AN UNINCORPORATED DIVISION OF WYETH, f/k/a WHITEHALL-ROBINS HEALTHCARE; &WHITEHALL LABORATORIES, INC.

Defendants.

CIVIL ACTION No. 3:03-CV-0167-R (BD)

JOINT STATUS REPORT ON PLAINTIFFS' MOTION AND BRIEF TO COMPEL DISCOVERY FROM DEFENDANT WYETH

TO THE HONORABLE JUDGE OF SAID COURT:

COME NOW La Sandra Madden and Levell Madden, Individually, and on Behalf of LaBrea Williams, a minor child, plaintiffs in the above numbered and styled cause, and file their Joint Status Report on Plaintiffs' Motion and Brief to Compel Discovery from Defendant Wyeth pursuant to the March 6, 2003 Standing Order on All Non-Dispositive Motions, and in support thereof would respectfully show the Court as follows:

I.
JOINT STATUS REPORT

A. NAMES OF ATTORNEYS WHO PARTICIPATED IN THE FACE-TO-FACE CONFERENCE

- James C. Barber - attorney for plaintiffs
- Jason S. Marina - attorney for plaintiffs
- Bill Sims - attorney for defendants
- Jeffrey J. Hobbs - attorney for defendants

B. DATE CONFERENCES WERE HELD AND AMOUNT OF TIME PARTIES CONFERRED

On July 21, 2003, Jason S. Marina, attorney, and Mark A. Mills, legal assistant, for plaintiffs and Jeff Hobbs for defendants held a face-to-face conference at the law office of Vinson & Elkins. The parties conferred for approximately one hour and thirty minutes. Partial agreement was reached at that time.

Then, on August 28, 2003, the individuals in subsection (A), above, held another face-to-face conference at the Law Offices of James C. Barber. The parties conferred for approximately two hours. Some additional agreements were reached at that time. Since that time, plaintiffs' counsel Barber and defense counsel Sims and Stahl have exchanged correspondence, and further clarified the parties' position on these issues.

C. MATTERS RESOLVED BY AGREEMENT

(1) Specific interrogatories

Interrogatory No. 3: Defendants have agreed to identify the pre-marketing clinical trials sought by identifying all such clinical trials for both prescription and over-the-counter (OTC) submissions to the Food and Drug Administration (FDA) by supplemental answer to this interrogatory in which defendants will reference such trials by NDA volume number. Defendants also agreed to produce the New Drug Applications (NDAs) for both prescription and OTC Childrens Advil which contain any pre-marketing clinical trials, subject to a final protective order entered by the court. Defendants will also identify all such clinical trials that exist in electronic format, and/or state that they do not exist. Finally, defendants will state that there are no other such clinical trials other than those listed in answer to this interrogatory.

Interrogatory No. 4: Defendants have agreed to identify the post-marketing clinical trials sought by identifying all such post-marketing clinical trials for both prescription and over-the-counter (OTC) submissions to the FDA by supplemental answer to this interrogatory, in which defendants will reference such trials by NDA volume number. Defendants have also agreed to

produce the NDAs for both prescription and OTC Childrens Advil which contain any post-marketing clinical trials, subject to a final protective order entered by the court. Defendants will also identify all such clinical trials that exist in electronic format, and/or state that they do not exist. Defendants have also agreed to go forward with the production of all NDAs in the paper format, subject to a final protective order entered by the court, by tendering them for inspection and copying. Finally, defendants will state that there are no other post-marketing clinical trials in their possession other than those listed in answer to this interrogatory.

Interrogatory Nos. 5 and 6: Defendants have agreed to check into the identity of any predecessor database(s) and to ensure that all information has been transferred to the GSSE S3 and/or WATSIN databases, and so state in answer to this interrogatory with verification. However, if such predecessor databases have *not* been transferred, defendants have agreed to identify such database(s) also by supplemental answer to this interrogatory.

Interrogatory No. 10: Defendants have agreed to supplement their interrogatory answer by providing the individual's title or designation, his or her address or phone number, an outline or his or her duties, and the dates of those duties.

Interrogatory No. 13: Defendants state they have produced all domestic advertising documents, but will not produce voluntarily any foreign advertising. Defendants will supplement their response to this interrogatory by identifying such documents by Bates numbers. Defendants have also agreed to provide dates or approximate dates that any domestic advertising agencies were retained.

Interrogatory No. 14: Defendants have agreed to supplement their response to this interrogatory by identifying labeling contained in the NDAs by NDA volume, and will produce such documents in conjunction with the production of the NDAs, subject to a final protective order entered by the court. Defendants will produce foreign labeling with their possession, custody, or control.

Interrogatory No. 15: Defendants have agreed to supplement their interrogatory answers by producing all U.S. pamphlets or brochures going back to 1989, in response to Request no. 21 of Plaintiffs Request for Production-First Set, and identifying such documents by Bates numbers in a supplemental answer to this interrogatory.

Interrogatory No. 17: Same agreements as to Interrogatory No. 13.

Interrogatory No. 18: Defendants have agreed to produce any Adverse Drug Experience (ADE) reports that involved adverse events or injuries that are listed in Request for Production No.9.

Interrogatory No. 19: Defendants have agreed to state in a supplemental response that there have been no other lawsuits involving Childrens Advil, and no notices of intent to file a lawsuit involving Childrens Advil.

(2) Specific Requests for Production

Request No. 3: Defendants have agreed to identify portions of the NDAs that were submitted to the FDA in electronic format, but have not agreed to produce these electronic submissions.

Request No. 4: Defendants have agreed to produce all responsive NDAs for inspection and copying in paper format, subject to a final protective order entered by the court. Defendants have agreed to Bates stamp any portions of the NDAs of which plaintiffs request copies. Defendants will withhold any ADE reports involving adverse events and injuries unrelated to those allegedly suffered by LaBrea Williams, but will produce those reports which concern the adverse events and injuries allegedly suffered by LaBrea Williams, as listed in Req. No. 9, below.

Request No. 5: Defendants have agreed to produce clinical trial data in paper format and in electronic format related to those adverse events or injuries allegedly suffered by LaBrea Williams, as listed in Req. No. 9 below. Defendants have agreed to Bates stamp any portions of the NDAs or other documents of which plaintiffs request copies.

Request No. 6: Defendants will produce adverse event reports from the relevant NDAs or other sources related to the adverse events or injuries allegedly suffered by LaBrea Williams, as listed in Req. No. 9 below. Defendants have agreed to Bates stamp any portions of the NDAs or other documents of which plaintiffs request copies.

Request No. 9: Defendants have agreed to drop their relevancy objections. Defendants have agreed to produce any electronic data from the CAMP study related to the adverse events and injuries listed in this request. Defendants are investigating whether they possess electronic data for the Boston Fever Study.

Request No. 10: Defendants will produce all ADE reports from the Boston Fever Study, if any exist, or the CAMP Study, related to the adverse events or injuries listed in Request No.9. Defendants have agreed to Bates stamp any portions of the NDAs or other documents of which plaintiffs request copies.

Request No. 11: Defendants have agreed to drop their relevancy objections, and will also state whether they have in their possession or have access to the data regarding renal problems in electronic format. Additionally, defendants will produce all ADE reports from the Boston Fever Study or the CAMP Study, if any, that they possess which are related to the adverse events or injuries allegedly suffered by LaBrea Williams, as listed in Req. No. 9, above.

Request No. 15: Defendants will produce all post-marketing ADE reports related to the adverse events or injuries allegedly suffered by LaBrea Williams, as listed in Req. No. 9 above, received by it from the time it first started distributing this drug by prescription to the present.

Request No. 16: Defendants have agreed to produce all ADE reports involving prescription and OTC Childrens Advil related to the adverse events or injuries allegedly suffered by LaBrea

Williams, as listed in Req. No. 9 above. Further, defendants have agreed to Bates stamp any portions of the NDAs or other documents of which plaintiffs request copies.

Request No. 17: Defendants have agreed to investigate what responsive policies and procedures exist beyond those already produced, and will produce any such procedures that are located. Defendants have agreed to Bates stamp any portions of the NDAs or other documents or which plaintiffs request copies.

Request No. 18: Defendants have agreed to produce all labels, tags, warnings, direction or instructions, domestic or foreign that are contained in all Children's Advil NDAs.

Request No. 20: Defendants have agreed to produce documents all ADE reports related to the adverse events or injuries allegedly suffered by LaBrea Williams, as listed in Req. No. 9 above, in paper or electronic format. Defendants have agreed to Bates stamp any portions of the NDAs or other documents of which plaintiffs request copies.

Request No. 21: Defendants have agreed to produce all domestic advertising documents for both prescription and OTC Childrens Advil. Defendants have also agreed to provide Bates stamp and/or NDA Volume and page number for all documents produced.

Request No. 22: Defendants agreed to produce any research studies that have been published and unpublished, related to the specific topics listed in this request, and/or defendants shall state that there are none, if none exist. Defendants will produce the published study done by Dr. Elizabeth Ashraf, et al. Further, Defendants have agreed to provide Bates stamp and/or NDA Volume and page number for all documents produced.

Request No. 23: Defendants have agreed to produce all sales manuals responsive to this request from 1989 to present. Defendants have agreed to Bates stamp any portions of the NDAs or other documents of which plaintiffs request copies.

Request No. 24: Defendants have agreed to produce a hard copy report from the Sales Forecasting System that reflects the total units of Children's Advil sold for the five years prior to LaBrea Williams's alleged injuries.

Request No. 26: Defendants will confirm in a supplemental response that there have been no other lawsuits involving Children's Advil.

Request No. 30: In addition to any responsive documents contained in the NDAs, defendants have agreed to produce relevant portions of any Periodic Safety Update Reports ("PSURS") dealing with Children's Advil. Defendants have agreed to Bates stamp any portions of the NDAs or other documents of which plaintiffs request copies.

Request No. 31: Defendants have agreed to produce all foreign ADE reports that are related to the adverse events and injuries allegedly suffered by LaBrea Williams, as listed in Req. No. 9

above.

Request No. 34: Defendants agreed to produce all studies in paper format that have been published or unpublished (in-house studies), if they exist, that evaluate the risk and benefit of Childrens Advil, its safety, or its efficacy, as specified in the request. Defendants have agreed to Bates stamp any portions of the NDAs or other documents of which plaintiffs request copies.

(3) Protective Order

The parties have agreed to all matters in the proposed protective order. The current draft of the Protective Order is attached as **Att. 1 to Jt. Rpt.**

(4) Inspection of the New Drug Applications (NDAs)

The parties have agreed to all aspects of the inspection of the NDAs, with the understanding that all copying and Bates stamping will be completed within seven days from the date the Plaintiffs provide Defendants with the identification of the documents that they would like copied.

D. SPECIFIC MATTERS THAT NEED TO BE HEARD AND DETERMINED

1) Specific Interrogatories and Requests For Production

Interrogatory No. 7 & Request No. 24: Sales information in electronic format.

Interrogatory No. 13 & Request No. 21: Detailed information about all advertising about the drug in question.

Interrogatory No. 14 & Request No. 18: Detailed information about all warnings, instructions, labels or package inserts ever distributed with the drug.

Interrogatory no. 18 & Req. Nos. 5, 6, 7, 8, 9, 10, 12, 15, & 16: Detailed information about all complaints of injury by the drug, and copies of all pre- or post-marketing Adverse Drug Experience Reports (ADEs), either during clinical trials or during the post-marketing period.

Req. Nos. 3 &4; and 13 & 14: All NDA (New Drug Applications).

Req. No. 6: Backup documentation for all ADEs.

Request Nos. 8 & 9: All clinical trials /post-marketing trials from Boston Fever Study and CAMP Study.

Request No. 10: All ADE reports from Boston Fever and CAMP Studies.

Request Nos. 11 & 12: All data in electronic or paper format regarding renal problems in children in the Boston Fever and CAMP Studies

Request Nos. 15 and 16: All post-marketing ADE reports.

Request No. 19: All warning labels on adult Advil.

Request No. 20: All drug defect, customer complaint, or adverse drug experience data bases.

Request No. 21: All advertising, foreign and domestic.

Request No. 22: Unpublished manuscripts.

Request No. 24: Sales data bases in electronic form.

Request No. 26: Lawsuit information about all ibuprofen drugs, including adult Advil.

Request No. 30: FDA inquiries and responses.

Request No. 31: Foreign ADEs from foreign clinical trials.

2) **Generic disputes (including some of the above)**

A) **Whether Wyeth's GSSE, S3, WATSIN, and sales information electronic databases should be identified and produced in their entirety and in electronic format.** (Interrogatory Nos. 5, 6, 7, and 18, and Request for Production Nos. 3, 5, 7, 9, 11, 13, 14, 15, 20, 24 and 34).

B) **Whether Wyeth should produce worldwide/international documents.** [Interrogatory 13 and Request for Production No 21: (worldwide/international advertising); Interrogatory 14 and Request 18 (detailed information about worldwide/international warnings, labels, etc); Interrogatory 15 and Request 21 (detailed information about worldwide/international brochures and pamphlets); and Request No. 31 (foreign ADEs from foreign clinical trials).].

C) **Lawsuits/notices of claims/labels pertaining to adult Advil (ibuprofen).** (Interrogatory No. 19 and Request for Production Nos. 19 & 26).

D) **Whether defendants are entitled to assert an objection/limitation on documents produced to those adverse events or injuries allegedly suffered by LaBrea Williams, or whether such objection has been waived:** (Interrogatory

no. 18 & Req. Nos. 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, & 31: Requesting detailed information about all complaints of injury by the drug, and copies of all pre- or post-marketing Adverse Drug Experience Reports (ADEs), either during clinical trials or during the post-marketing period.).

E. REASONS WHY AGREEMENT COULD NOT BE REACHED

1. Plaintiffs' Position on Specific Interrogatories and Requests

Interrogatory No. 7 & Request No. 24: Sales information in electronic format. Defendant has offered to produce hard copy printouts of the data base containing this information, and plaintiffs are seeking it in electronic format. As argued below under Generic Issues, electronic data is clearly discoverable, along with the software necessary to access it, if plaintiffs have shown good cause for obtaining it, and they have. Defendants claim that some of the sales data is highly confidential, but without at least having a description of the contents, plaintiffs cannot respond to this. However, this can be dealt with by the Protective Order that the parties have agreed to.

Interrogatory No. 13 & Request No. 21: Detailed information about all advertising about the drug in question--objections to foreign ads have been waived. Three months ago, when they filed their initial responses, defendants initially agreed to produce *all* advertising, domestic and foreign, without objection, in response to Req. No. 21. In the face to face conference, Mr. Sims, lead counsel for defendants, further agreed to provide all such advertising back to 1989. However, they have now reneged on this agreement entirely, and are refusing to produce foreign advertising. All advertisements are obviously relevant. Suppose they admit in foreign advertising that SJS/TEN or related skin conditions are a greater risk than they admit in their American ads? But at bottom they have waived this objection.

Defendants' argument that plaintiffs did not seek foreign advertisements is meritless. The request seeks "Copies of *all* advertisements published by you in medical journals or other periodicals, or in the print or broadcast media, at any time regarding the drug in question." (emphasis added). All means all, including foreign advertisements. Nor will defendants' offer to produce those ads that specifically reference SJS (or related skin conditions) suffice, because there are other conditions involved in this case, such as renal toxicity.

Interrogatory No. 14 & Request No. 18: Detailed information about all warnings, instructions, labels or package inserts ever distributed with the drug. Defendants have not answered this interrogatory at all, but rather have referred plaintiffs to documents in the NDAs. As a compromise, they have offered to identify such labeling by NDA volume, but are ambivalent about producing foreign labeling, by limiting it to what's contained in the NDAs for Children's Advil. Plaintiffs want a complete answer to Interrogatory No. 14, because the verbatim contents of all labels and package insert, and when they were in effect, is essential to this failure to warn case. Additionally, plaintiffs want all foreign labeling, without qualification. Again, the relevance is apparent: if they warn about SJS/TEN in a foreign label, or warn more

prominently, that is an admission against interest in the present case. Defendants claim that a tender under Fed. R. Civ. P. 33(d) is adequate, but the tender is not complete, because they do not tender *all* such labeling, but only the labeling in the NDAs. Plaintiffs also need to know and are entitled to know *when* the labels or warnings were in effect, and defendants have thus far refused to provide this information.

Req. Nos. 3 &4; and 13 & 14: All NDA (New Drug Applications) are clearly discoverable, in their entirety, without restriction, and any objections are waived. The NDA is the document that contains the research data, the pre-marketing clinical trials data, the FDA Medical Officers Review of the application, and a myriad of relevant data regarding a drug product liability case. Defendants initially agreed to produce all NDAs for Childrens Advil without restriction, and confirmed that agreement in the face-to-face conference. (*See, e.g, defendants' response to Req. No. 4: "Wyeth will produce documents responsive to this request at a mutually agreeable time and place, subject to an appropriate protective order.")* (emphasis added).

However, now defense counsel is reneging on that agreement and is attempting to limit their production by (withholding) any ADE reports involving adverse events an injuries unrelated to those allegedly suffered by LaBrea Williams. (*See, Agreement as to Req. No. 4, above.).* For the reasons stated above, any objections to this discovery have been waived. Additionally, plaintiffs are entitled to any portions of the NDAs that exist in electronic format, and the software manuals necessary to access them.

Request No. 6: All backup documents for ADE reports. This request has been limited by agreement at defendants' request to medical records, statements, or follow up reports, relating to ADEs associated with the drug. However, although defendants did not object to this request initially, and thus waived any objection, they are now objecting and attempting to limit their tender of these documents to any adverse events that are of the same kind as those alleged by LaBrea Williams. This objection has been waived, for the reasons shown above and below, and the documents sought are clearly relevant.

Request Nos. 8 & 9: All clinical trials /post-marketing trials from Boston Fever Study and CAMP Study are clearly discoverable, and any objections are waived. The Boston Fever Study and the CAMP Study are the two basic clinical trials relied on by defendant to obtain FDA approval of this drug for prescription and OTC sales. Again, in their response to Req. No. 8 initially served on plaintiffs, defendants stated that these documents *"are contained in the NDAs for Childrens Advil...(and) will be made available for inspection and copying at a mutually agreeable time and place..").* Thus, any objection to producing all clinical trials data from these studies is waived.

Although they initially objected to Req. No. 9, based on relevancy, they have dropped that objection, and agreed to produce any electronic data from the Boston Fever Study or CAMP study relating to the *skin conditions* listed in Req. No. 9. However, they have refused to produce software manuals responsive to this request. Defendants also have refused to produce all case

reports and ADE reports from all clinical trials involving prescription and OTC Childrens Advil clinical trials, but rather are limiting their production to the skin conditions listed in this request.

Request No. 10: All ADE reports from Boston Fever and CAMP Studies are discoverable, and any objections have been waived. They initially tendered *all* paper ADE reports from Boston Fever and CAMP, but now are attempting to limit it to those skin conditions described in Req. no. 9. They have waived any objections to this request.

Request Nos. 11 & 12: All data in electronic or paper format regarding renal problems in children in the Boston Fever and CAMP Studies are clearly relevant, and any objections are waived. Renal toxicity is an adverse effect associated in the literature with this drug. Indeed, the National Kidney Foundation has recommended to the FDA in 2002 that a warning be included on OTC ibuprofen about kidney toxicity, because 94 deaths have been attributable to it. **(Att. 2 to Jt. Report).** Additionally, the medical records show that LaBrea Williams, the minor plaintiff in this case, sustained renal damage. **(Att. 3 to Jt. Report-Excerpt from hospital records).** Thus, data about adverse events involving renal toxicity is therefore clearly relevant.

Additionally, in their initial response to Req. No. 12, no objection was made to this request, and defendants stated that such documents were contained in the NDAs, and would "*be made available for inspection and copying at a mutually agreeable time and place....*" Thus, defendants' attempt to limit their tender to the adverse events or injuries allegedly suffered by LaBrea Williams should be rejected.

Request Nos. 15 and 16: All post-marketing ADE reports are clearly discoverable, and any objection to them as part of the NDAs has been waived. They didn't object to producing the complete NDAs in their responses, or at the face-to-face conference, including all ADEs (w/o restriction), and all underlying paper documentation to them; but now they are attempting to limit them to the adverse events or injuries allegedly suffered by LaBrea Williams. This objection has been waived.

Request No. 19: All warning labels on adult Advil are likewise discoverable. Although their objection to this request was timely, any such warnings or labels distributed with adult Advil are clearly relevant and discoverable, because the ingredients are identical. Both drugs contain as their active ingredient ibuprofen, and the only apparent difference is that Childrens Advil contains smaller amounts.

Request No. 20: All drug defect, customer complaint, or adverse drug experience data bases. Although they objected to this request for different reasons, they previously agreed to produce documents containing information about Childrens Advil responsive to this request, subject to their objections, but are now attempting to limit their production to adverse events or injuries allegedly suffered by LaBrea Williams. This specific objection was not made, and was thus waived for the reasons stated above. Further, this information is clearly relevant.

Request No. 21: Foreign advertising. They have only agreed to produce domestic advertising,

and we seek foreign advertising as well. Clearly, foreign advertising is relevant, and could contain admissions about the causal relationship of Childrens Advil to SJS/TEN, or different warnings, or a myriad other admissions against interest. It would be ludicrous for defendants to have a big, bold, black box warning for this condition in Europe, for example, but not in the U.S.

Request No. 22: Unpublished manuscripts. We want all drafts or manuscripts of the Ashraf study also, and although they are agreeing to produce the final study, they will not produce the drafts and manuscripts which could contain helpful admissions before rewriting by the drug company. If there are no such drafts, defendants can so state. However, their objection to producing them should be denied. They are clearly relevant. Suppose the defendants rewrote an article to downplay the relationship between Children's Advil and skin problems, such as SJS? They are relevant and discoverable.

Request No. 24: Sales data bases in electronic format. They initially failed to object to producing all data bases showing the total number of bottles of pills, or total number of pills sold over a given period, and said that they would produce documents responsive to this request. They also agreed to do so at the face-to-face conference in electronic format. However, they are now reneging on this promise. Such data is discoverable in electronic form, as shown below.

Request No. 26: Lawsuit information about all ibuprofen drugs. We want lawsuit information about all ibuprofen drugs, including adult Advil, and they are only agreeing to produce such information about Childrens Advil. Defendants' argument that Adult Advil is not similar is absurd---it is the same drug, only in different dosages.

Request No. 30: FDA inquiries and responses. We are entitled to all FDA inquiries and their responses, and they agreed to produce these documents without qualification in their responses, and are now attempting to limit them.

Request No. 31: Foreign ADEs from foreign clinical trials. We have requested and are entitled to all foreign ADEs from all foreign clinical trials, not just limited to the adverse events and injuries allegedly suffered by LaBrea Williams. And additionally, they agreed to produce such documents without objection in their responses, and any such objections are waived.

2. Defendants' Position on Specific Interrogatories/Requests

The issues presented here in connection with individual discovery requests are generally duplicative of the issues described subsequently in section E(3), below, where "common" issues are grouped together and discussed on a topic-by-topic basis. To avoid unnecessary duplication, Wyeth's principal discussion of each such topic area is presented in section E(3).

Interr. 7 and RFP 24: This topic is addressed below in section E(3)(B), in connection with the general issue of when electronic production of documents should be provided. As pertinent here, the sought-after data does not consist of some massive database of numbers for which an ability to electronically manipulate the data is essential. To the contrary, the sought-after data consists solely

of the total number of Childrens Advil pills sold on an annual basis. While Wyeth does maintain a larger sales information database from which the pertinent data has been extracted and produced in hard copy form, that database consists of highly confidential material that not even plaintiffs' expert has claimed a need to review. In short, Plaintiffs want annual sales figures so they can determine the prevalence of certain adverse events relative to the overall number of pills sold. This data is not the "sales information database," but only a very narrow portion of it. In fact, it consists of mere line-items that should be produced in a brief, hard copy format.

Interr. 13 and RFP 21: Plaintiffs' discovery requests did not *seek* foreign advertising. While the requests sought "all advertisements," this was clarified to mean all advertisements placed by the Defendants, which are American entities, not by any of their foreign "affiliates." Plaintiffs now suggest that by defining "Wyeth" to include "Wyeth's agents," the request included not only advertisements placed by Wyeth, but also advertisements placed by "Wyeth's foreign affiliates," as though "agent" and "affiliate" were interchangeable terms. They are not.

If Plaintiffs had made requests which encompassed advertisements placed by Wyeth's foreign affiliates, an objection by Wyeth would have been proper. Plaintiffs do not dispute that they saw no foreign advertisement. Instead, Plaintiffs only claim a need to see foreign advertisements just in case "Wyeth" admitted in those ads that the use of Childrens Advil creates a significant risk of Stevens-Johnson Syndrome (or related skin conditions). To address that concern, Wyeth will agree to produce any such ads in their possession, custody, or control that reference Stevens-Johnson Syndrome (or related skin conditions), but believe that none exist.

In accordance with Plaintiffs' breakdown of the issues, these arguments are largely repeated in Section E(3)(D).

Interr. 14 and RFP 18: Plaintiffs are asking Wyeth to re-type, word-for-word, the information on labels that Wyeth is already agreeing to produce. Such a request is unwarranted. Fed. R. Civ. P. 33(d). With respect to foreign labels, Wyeth has already agreed to produce those labels within its possession, custody, or control.

RFP 3, 4, 13 & 14: Wyeth has agreed to provide the Childrens Advil NDAs, except for injury reports which are unrelated to the skin injuries claimed by Plaintiffs in their petition. The relevance and discoverability of those other documents underlies a number of the parties disagreements, and Wyeth addresses this common issue in detail below, in Section E(3)(H).

RFP 6: The only dispute here concerns the relevance and discoverability of injury reports which are unrelated to the skin injuries claimed by Plaintiffs in their petition. Wyeth addresses this common issue in detail below, in Section E(3)(H).

RFP 8 & 9: The only dispute here concerns the relevance and discoverability of injury reports which are unrelated to the skin injuries claimed by Plaintiffs in their petition. Wyeth addresses this common issue in detail below, in Section E(3)(H).

RFP 10: The only dispute here concerns the relevance and discoverability of injury reports which

are unrelated to the skin injuries claimed by Plaintiffs in their petition. Wyeth addresses this common issue in detail below, in Section E(3)(H).

RFP 11 & 12: Plaintiffs' requests for Wyeth's records of injury reports involving kidney damage should be rejected for the reasons addressed in detail in Section E(3)(H), below. There is no allegation in the petition that LaBrea Williams's ingestion of Childrens Advil caused renal toxicity. Moreover, even assuming that plaintiffs will claim that LaBrea Williams suffered renal damage as a secondary injury arising from Stevens-Johnson Syndrome (which has not been alleged to date), that would be a different sort of claim from an assertion that the drug directly caused renal toxicity. In that event, any effort by Plaintiffs' to obtain discovery concerning whether there is a ***direct*** association between Children's Advil and renal toxicity (as opposed to the ***indirect*** association intermediated by Stevens-Johnson Syndrome) would not likely to lead to relevant evidence in this case.

RFP 15 & 16: The only dispute here concerns the relevance and discoverability of injury reports which are unrelated to the skin injuries claimed by Plaintiffs in their petition. Wyeth addresses this common issue in detail below, in Section E(3)(H).

RFP 19: The dispute here concerns the relevance of safety reports from ***adults*** who use Adult Advil. Wyeth addresses in detail below, in Section E(3)(F), the common issue of whether evidence concerning adult Advil would be probative in this case.

RFP 20: The only dispute here concerns the relevance and discoverability of injury reports which are unrelated to the skin injuries claimed by Plaintiffs in their petition. Wyeth addresses this common issue in detail below.

RFP 21: This request was addressed above. *See supra* (concerning Interrogatory No. 13 and Request for Production No. 21).

RFP 22: Plaintiffs seek *drafts* of an article written by Dr. Elizabeth Ashraf et al., who are Wyeth employees. Plaintiffs will receive the article, itself. By definition, any drafts of the article would have never been seen by Plaintiffs (or any person through whom Plaintiffs might claim indirect reliance) and cannot be claimed to be relevant for that purpose. Instead, Plaintiffs only suggest without any factual basis that the drafts may reveal some awareness about Stevens-Johnson Syndrome that was intentionally hidden in the final article. Even assuming that Plaintiffs had a legitimate basis for such a concern, which they do not, that basis would be addressed by Wyeth agreeing to produce any drafts of the article in which Stevens-Johnson Syndrome had been discussed differently, but there never was any such draft.

RFP 24: This request was addressed above. *See supra* (concerning Interrogatory No. 7and Request for Production No. 24).

RFP 26: The dispute here concerns the relevance of lawsuits filed by adults who use ***adult*** Advil. Below, in Section E(3)(F), Wyeth addresses in detail the common issue of whether adult Advil information is pertinent in a Childrens Advil case. Separately, Plaintiffs' request is further

unreasonable because it involves lawsuits that have nothing to do with the Stevens-Johnson Syndrome allegations raised in this case. *See, e.g., Uniroyal Goodrich Tire Co. v. Martinez*, 977 S.W.2d 328, 340-41 (Tex. 1998) (under analogous Texas rules, relevance of other lawsuits depends upon predicate showing that they are substantially similar).

RFP 30: The only dispute here concerns the relevance and discoverability of documents which are unrelated to the skin injuries claimed by Plaintiffs in their petition. Wyeth addresses this common issue in detail below, in Section E(3)(H).

RFP 31: The only dispute here concerns the relevance and discoverability of injury reports which are unrelated to the skin injuries claimed by Plaintiffs in their petition. Wyeth addresses this common issue in detail below, in Section E(3)(H).

3. Parties' Positions on Generic Issues

A. Plaintiffs' position on production of information in electronic format

i) Plaintiffs' request that Wyeth provide electronic information in a readable, searchable and usable format that will enable plaintiffs' counsel and their experts the ability to adequately utilize the information.

Plaintiffs have made several requests that include large volumes of information and data that are stored in databases. Wyeth has specifically identified four relevant databases, contrary to defendants' assertion on pg. 19, *infra*, that there are only two: 1) the Global Safety Surveillance & Epidemiology (GSSE), which contains ADE information on all defendants' drugs worldwide; 2) S3, which is apparently a predecessor global ADE data base; 3) WATSIN, which contains ADE worldwide data and consumer complaints; and 4) a sales information data base.[1] Further, because the defendant maintains such information in a machine-readable and searchable format in the regular course of their business, it is absolutely necessary the plaintiffs be provided the electronic data and the software and manuals to retrieve such information.

ii) Electronic data is discoverable and should be produced in a readable format.

[1] These data bases are discussed in detail in **Att. 5, Defendants' Policy 405.**

Between the Rules of Civil Procedure, the various civil practice guides, the practicalities of pharmaceutical business enterprises, and common sense, it is axiomatic that electronic data is discoverable and should be produced. *See* Case Management and Electronic Discovery in Pharmaceutical Litigation, Obtaining from Pharmaceutical Defendants Electronically Maintained Data and Information, at C-9 (2003).

The following cases have held that relevant electronic data is discoverable and should be produced: *Anti-Monopoly, Inc. v. Hasbro, Inc.,* 1995 U.S. DIST. LEXIS 16355, *4–5 (S.D. N.Y. 1995) (". . . it is black letter law that computerized data is discoverable if relevant," even where the defendant intends to produce the information in hard copy.); *Santiago v. Miles,* 121 F.R.D. 636, 640 (W.D. N.Y. 1988) ("A request for raw information in computer banks is proper and the information is obtainable under the discovery rules.").

Additionally, the following cases permitted the production of information and documents in an electronic format with the equipment and software to be able to utilize such information: *See Sattar v. Motorola, Inc.,* 138 F.3d 1164, 1171 (7th Cir. 1998) (defendant produced 210,000 pages of e-mails in the form of computer tapes, but plaintiff lacked the equipment and software to read it; the court ordered the defendant to choose between downloading the data to conventional computer disks or loaning the plaintiff a copy of the necessary software or offering plaintiff onsite access to its own system); *see also*, *Anderson v. Cornejo*, 2001 WL 219639 (N.D. Ill. 2001) (plaintiff was permitted production of computer database and computer readable format concerning customs activity for statistical analysis); *Crown Life Ins. Co. v. Craig,* 995 F.2d 1376, 1383 (7th Cir. 1993) (Rule 34 contemplates party must make data available in accessible form).

iii) Plaintiffs will be severely prejudiced by denying them this data in electronic format.

Further, much of the data sought will have to be statistically analyzed and this can only be done conveniently and efficiently on computer. **(Att. 4 to Jt. Rpt., Affidavit of Dr. Nicar, pg. 4 & Suppl. Affidavit of Dr. Nicar).** Plaintiffs' consulting expert, Dr. Rusty Nicar, a toxicologist and epidemiologist, has stated that defendants' Worldwide Adverse Event Data Base (the GSSE S3 data base) has the ability to track, monitor and produce reports regarding adverse events associated with this drug. This statement is supported by the policy itself, which is **Att. 5.**

All adverse drug events worldwide that are associated with a drug product are required to be reported to this database. Thus, if it is not provided in electronic format as it exists, plaintiffs will be required to re-input it into electronic format, so that it can be analyzed by experts. Contrary to defendants' assertion that it will be inconvenienced, plaintiffs will be far more inconvenienced by having to re-invent the wheel, by re-inputting the data in order to analyze it.

Defendants claim that none of the data in electronic form is statistical data that can be analyzed electronically. However, as shown by Dr. Nicar's affidavit, its GSSE, S3 and WATSIN data bases do contain data about all the ADEs reported to the defendant regarding this drug and other Wyeth drugs worldwide, and this information will have to be re-inputted into the computer in order to adequately analyze it electronically without these data bases. Plaintiffs should make clear that we are not seeking such information about *all* drugs, but only ibuprofen drugs.

Additionally, plaintiffs also seek defendants' sales information data base, which it has also acknowledged exists. Plaintiffs need the sales data bases in order to analyze the incidence of ADEs involving SJS/TEN and related conditions caused by ibuprofen. Defendants will undoubtedly argue that SJS is a rare reaction to its drug, and plaintiffs will therefore need the

electronic data showing total number of doses sold, etc., in order to accurately analyze the percentage of ADEs per doses sold. This data base may also show an estimate of doses taken as well, which would probably be less that doses sold, and would probably give a better indication of the incidence rate of adverse effects from the drug.

Defendants' argument that plaintiffs have not sought their entire sales information data base is false. Plaintiffs' pertinent request, Req. no. 24, seeks "*all data bases created and maintained by you that contain total number of bottles of pills, or total number of pills sold over a given period of time*," and defendant answered "*defendant will produce documents responsive to this request*." Aside from the fact that defendant did not object to producing its entire sales data base in electronic form, and thus waived this objection, as argued below, this request is clearly broad enough to include it.

Additionally, defendants' argument that this data base contains highly confidential sales information is impossible to evaluate, without some indication of what data is on the data base. One of the major problems in proving causation and risk of adverse side effects is the lack of denominator data, to be used to determine the absolute or relative risk of a certain side effect. What is needed ideally is the exact number of patients exposed to the risk. However, this data is often unavailable, so that estimation of the exposure can be shown by using drug utilization data. [*See,* Goldman, M.D., USFDA, Limitations and Strengths of Spontaneous Reports Data, *Clin Therapeutics,* Vol. 20, Supp. C (1998), pg. C41] **(Attached as part of Att. 10).**

This type of data can include market surveys based on sales or prescription data, third-party payers or health maintenance organizations, institutional/ambulatory settings, or specific pharmaco-epidemiological studies. *Id.* Without discovering the defendants' complete data base,

or at the very least documents showing what information is on it, plaintiffs cannot determine whether only part or all of it is relevant and discoverable.

Defendants' argument that production of the paper records they choose to produce is all that is pertinent to plaintiffs' request is groundless. As Dr. Nicar's affidavit also shows, and as discussed *infra* under the issue of limiting the ADE data produced to skin conditions, *all* of the adverse event data is relevant to the analysis of whether or not some reactions have been improperly coded under inappropriate diagnostic terms. Additionally, defendants' arguments that it will be burdened by the production of the electronic information groundless and without support in defendants' papers.

Finally, defendants' argument that it is improper for plaintiffs to review the analysis done by the FDA is a joke! As reported by the *Wall Street Journal* on Jan. 28, 2003, much test data from so-called Phase IV post-marketing studies promised to the FDA is long overdue. The article cites scores of drugs that have been preliminarily approved by the FDA, subject to the completion of further testing.

However, according to the article, "fewer than half of the studies tracked by the FDA as of February 20002 had been completed.... Says U.S Rep Bart Stupak, a Michigan Democrat: Phase IV studies . . . are nightmarishly inadequate, and neglected to a shameful extent by both the FDA and drug manufacturers." Although it is not known at this time whether defendant Wyeth has committed to further Phase IV studies on Childrens Advil, it *is* widely known that the FDA is understaffed and underfunded, and unable to complete the type of detailed analysis that plaintiffs propose in this case.

B. <u>Defendants' position on the production of information in electronic format.</u>

Each of the documents that Plaintiffs seeks in electronic format is being made available in hard copy. Wyeth recognizes that the production of documents in electronic form can *sometimes* be appropriate, but there is no entitlement to an electronic production, and the rationales urged for justifying an electronic production in the cases cited by Plaintiffs are inapplicable here. Unlike those cases, an electronic production of the relevant data will provide no meaningful benefit to Plaintiffs in this case, but will, instead, place an unfair burden on Wyeth by preventing Wyeth from withholding from production information that is confidential and irrelevant.

Plaintiffs have identified two databases that they seek: (1) Wyeth's sales information database, which contains detailed financial data on the company's operations; and (2) Wyeth's Adverse Event database, which lists and contains documentation on every adverse event suffered by every user of every Wyeth product. While Plaintiffs' expert is correct that these large databases are easier to navigate when they are in an electronic format, that conclusion begs the pertinent question: should Plaintiffs be entitled to the entire databases or just to portions of the databases? As argued below, Plaintiffs should only be entitled to specific data within these databases – indeed, for the sales information database, Plaintiffs have not even suggested why they may want anything further. And, once we focus on the specific data to which Plaintiffs are entitled, it can be seen that there is no reason to produce ***that*** data electronically.

Plaintiffs bear the burden of demonstrating that they need documents in electronic form. *McNally Tunneling Corp. v. City of Evanston*, 2001 U.S. Dist. LEXIS 20394, *14 (N.D. Ill. 2001) (party seeking discovery has the burden of establishing that hard copies of computer files are insufficient). Here, Plaintiffs cannot meet this burden because: (1) they cannot establish a need for the ***pertinent*** information in electronic format; and (2) Wyeth would be unfairly burdened if forced

to comply with Plaintiffs' requests. *See Williams v. Owens-Illinois, Inc.*, 665 F.2d 918, 932-33 (9th Cir. 1982) (computer tapes did not need to be produced where "[a]all information contained on the computer tapes was included in the wage cards which appellants discovered. Appellants were therefore not deprived of any data.").

With respect to the sales data, Plaintiffs have not ever seriously suggested that they would be entitled to Wyeth's entire sales information database. All that Plaintiffs' expert has said he needs is data showing the total number of Childrens Advil pills sold on an annual basis. *See* Nicar Affid. ¶ 10 ("I am asking for Wyeth to provide amount of bottles sold in the USA for Advil, and Childrens Advil, for each year since approval of the drugs for sale in the USA."). The responsive data – which are mere line items for the handful of years that Childrens Advil has been marketed – are in no way "voluminous" and there is no need or advantage to have them produced electronically. In fact, if Plaintiffs want to run calculations using these handful of figures, it would take more effort to write computer code to read figures from one spreadsheet and transpose them into another for making a calculation than it would to manually type in the annual sales numbers. The same would be true for adult Advil's sales numbers. This is simply not the type of cumbersome data that needs to be in electronic form to preserve its manageability. What would be voluminous is the rest of the sales information database, but there is no reason Plaintiffs can give for needing that additional data.

Wyeth also maintains clinical data which it has produced to the FDA in electronic form. This clinical data represents the results of investigations undertaken to determine whether there is any causal relationship between Childrens Advil and a wide range of afflictions which are wholly unrelated to those alleged by Plaintiffs in this case. While providing such an exhaustive database to

the FDA makes sense so that the FDA can address the comprehensive issue of the total risks associated with a drug (e.g., to answer questions like how many gastrointestinal events are there? and how many total adverse events are there?), Plaintiffs' attempt to cast themselves in the role of reviewers of the FDA's approval of Childrens Advil is excessive, as discussed in detail below in Section E(3)(H)(2). To the extent that Plaintiffs need such macro-data (which they do not), gross reports of the compiled data are already published. There is no need for Plaintiffs to have the detailed data on any of these adverse events that are not alleged to have been suffered by Plaintiff LaBrea Williams.

What Plaintiffs should be entitled to are the specific data (i.e., the adverse event reports) relating to LaBrea Williams' injury. For this subset of data, there is no advantage to having an electronic production. These pertinent documents are not the type of documents which contain statistical data that Plaintiffs need in electronic form so that they can perform some sort of statistical analysis. Plaintiffs erroneously hypothesize that the adverse event database can be manipulated sort of like the internet, with "click-thru" links that would allow a user to flip between "related" documents which are all linked together in some fashion. In fact, the adverse event database is not like the internet. It is more or less the electronic equivalent of a filing cabinet. A person who wants to "call up" a particular report has to go to the database, open up a folder assigned to a particular report, and look inside – no different from a person who had a filing cabinet of hard copy reports. *See* Affidavit of Gerard Boccuti ¶¶ 3-4 (attached as **Attachment 8**).

There are, of course, situations where an electronic production provides unique, substantial benefits, and Plaintiffs have cited cases reflecting those situations. There, however, the reason the computerized data is necessary is because the party seeking discovery has a need to manipulate the

data in order to perform some statistical analysis that cannot be provided by a hard-copy production, given the time it would take, and the element of human error it would introduce, to perform the statistical analysis by hand. The only instance in which Plaintiffs' expert has identified a situation where he would like to run statistical calculations has to do with his expressed desire to conduct a thorough re-examination of the entire Children's Advil product (mimicking the process the FDA undertook when it approved Children's Advil originally). However, that sort of statistical analysis falls well beyond the legitimate grounds of this lawsuit. *See supra* Section E(3)(H)(2)(b) (demonstrating that Plaintiffs are not entitled to put Children's Advil on trial). In fact, there is no legitimate purpose that would be served by providing electronically the documents that Plaintiffs seek.

Against this absence of a legitimate benefit to electronic production, the Court should weigh the burden that producing these documents in electronic form will place on Wyeth. With a hard copy production, Wyeth has the ability to carve out confidential and proprietary information that has no bearing on this case. The sales information database is a good example. Instead of turning over the entire database, Wyeth has agreed to extract the annual sales data which will enable Plaintiffs to "accurately analyze the percentage of ADEs per doses sold," just as Plaintiffs have sought they would like to do. *See supra.* Producing the adverse event database electronically would also expose confidential information, e.g., patient identifying information, which is protected under HIPAA. *See* 45 C.F.R. § 164.512(b)(1)(iii). Wyeth cannot "redact" line items in an electronic document, but can only do so when the document is printed into a hard copy.

C. <u>Plaintiffs' position on worldwide advertising materials, warnings & labels, pamphlets &brochures distributed with the drug, and foreign ADEs.</u>

With respect to Interrogatory No. 13 and Request for Production No 21 (domestic and foreign advertising); Interrogatory No. 14 and Request No. 18 (domestic and foreign labels, tags, warnings, etc.; Interrogatory No. 15 and Request No. 21 (domestic and foreign pamphlets, brochures, etc; and Req. No. 31 (ADEs from foreign clinical trials), defendants have now agreed to produce only foreign labeling. *(See, Agreement as to Int. no. 14 and Req. no. 18, above).*

However, foreign advertising, labels & warnings, and pamphlets and brochures are equally relevant to this drug product liability case. Defendants argue that plaintiffs did not seek foreign advertising, and have never seen foreign ads, and therefore they are not relevant. First of all, the assertion that plaintiffs did not seek foreign ads is false. The request seeks "*Copies of all advertisements published by you in medical journals or other periodicals,"* without limitation, and once again, defended responded "***we will produce documents responsive to this request".*** Now, defendants are attempting to parse the request to carve out foreign ads, claiming that plaintiffs only sought American ads, and not ads by foreign subsidiaries.

The definition of "defendant, you, and your" included "any and all agents, servants, employees, and other representatives of Wyeth, d/b/a Wyeth, Inc., f/k/a American Home Products Corporation; Wyeth Consumer Healthcare, an unincorporated Divison of Wyeth, f/k/a Whitehall Robins Health Care; and Whitehall Laboratories, Inc." This is clearly broad enough to include Wyeth and all its subsidiaries, domestic and foreign.

Nor is defendants' contention of any merit that because plaintiffs have never seen foreign ads, they are not relevant. First, much of pharmaceutical advertisement is directed to physicians anyway, and not consumers, and this is particularly true of Childrens Motrin, which

was initially sold by prescription only. Additionally, how the same drug company advertises and/or markets the same or substantially similar products in a different country is reasonably calculated to lead to the discovery of admissible evidence, especially with regard to plaintiffs' allegations of failure to warn/inadequate warning.

For example, if the defendants ran an advertisement in a foreign medical journal containing a more detailed warning about SJS/TEN, the catastrophic skin condition involved in this case, but omitted it in the U.S. in similar medical journal advertising, the relevancy and admissibility of such admissions is obvious, particularly where as here the defendant has indicated that it will deny that its product causes SJS. This is just one example.

Other examples could be that defendants warned that the risk of SJS was greater than 1%, unlike its domestic ads which place the risk at less than 1% if it is mentioned at all. Or suppose their ads stated that if the patient presented with a rash, the drug should be stopped immediately; or, that if the patient presented with stomatitis (sore mouth), a condition clearly related to SJS in the literature, that the drug should be stopped immediately? *All foreign advertising by defendants for ibuprofen drugs is relevant because it may contain admissions against interest by defendant that have direct bearing on the present case!* Likewise, foreign reports of ADEs associated with Childrens Advil are just as relevant to show the risk if they are from Europe as if from the United States. To assert otherwise is ludicrous.

D. <u>Defendants' position on worldwide advertising materials, warnings & labels, pamphlets & brochures distributed with the drug, and foreign ADEs.</u>

Plaintiffs seek foreign adverse event reports, foreign labels, and foreign advertising. With respect to the adverse event reports, Wyeth is producing all those within its possession, custody, or

control which pertain to the relevant symptoms. *See* Section E(2), above, RFP 31.

With respect to foreign labels, Wyeth has agreed to produce those within its possession, custody, or control.

With respect to the advertising, as demonstrated above, Plaintiffs' discovery requests did not *seek* advertising placed by Wyeth's foreign affiliates. *See* Section E(2), above, Interr. 13 and RFP 21. Had they done so, the request would have been improper inasmuch as Plaintiffs do not contend that they saw any foreign advertisement. *See In re Norplant*, 955 F. Supp. 700, 708 (E.D. Tex. 1997), *aff'd*, 165 F.3d 374 (5th Cir. 1999) (finding advertising of Norplant immaterial when Plaintiffs admit they never saw such advertising prior to their implantation). Instead, Plaintiffs only claim a need to see foreign ads just in case Wyeth admitted in those ads that the use of Children's Advil creates a significant risk of Stevens-Johnson Syndrome (or related skin conditions). To address that concern, Wyeth will agree to produce any such ads in their possession, custody, or control that reference Stevens-Johnson Syndrome (or related skin conditions), but believe that none exist.

E. <u>Plaintiffs' position on lawsuits/notices of claims/labels involving adult Advil (ibuprofen)</u>

In response to Interrogatory No. 19 and Request for Production Nos 19 & 26, defendants object to identifying and/or producing documents concerning lawsuits/notices of claims/labeling involving adult Advil. As defendants point out, only one of these requests relates specifically to Adult Advil, but all three are broad enough to include information about Adult Advil in their scope. Defendants claim that the definition of the drug is not broad enough to include adult Advil. However, this is clearly false. The definition states, in pertinent part, "the term 'the drug' as used

hereinafter in these interrogatories shall mean the nonsteroidal anti-inflammatory drug called Childrens Advil, ***generic name ibuprofen, regardless of what trade name was used to refer to it".*** (emphasis added), and this clearly includes adult Advil, which contains the same active ingredient as Childrens Advil, except for the dosage. Thus, it is the same drug, as shown by **Att. 4, Affidavit and Suppl. Affidavit of Dr. Rusty Nicar.**

Additionally, as defendants point out, Req. No. 19 refers expressly to adult Advil. It seeks: "*All warnings, instructions, labels, or package inserts ever distributed with adult Advil at any time.*" Thus, this request refers directly to adult Advil, without regard to the definition of the drug. As to this request, defendant coyly switches gears, now claiming that any information about Adult Advil is irrelevant. Clearly, it is not.

Both drugs contain the active ingredient ibuprofen, which is a propionic acid derivative, and when it is discussed in the medical literature, it is discussed as ibuprofen, not Advil or Motrin. For example, when the World Health Organization rejected it recently as an effective pain medicine for children, it discussed it generically as follows:

> Ibuprofen is a non-steroidal anti-inflammatory drug with established analgesic, anti-inflammatory and antipyretic (anti-fever) properties. It is a propionic acid derivative and is licensed for adult and pediatric use in many countries. **(Att. 6, WHO document).**

The drug is ibuprofen, and it is identical, whether it is called Childrens Advil, Adult Advil, or Childrens or Adult Motrin, its competitor. Certainly the pharmacokinetics of the drug are different with adults and children, but the medical and drug literature does not distinguish between the drugs in their basic indications, contra-indications, and adverse effects.

i) Information about similar products is generally discoverable.

As shown by the Affidavits of Dr. Rusty Nicar, adult Advil has the same active ingredient

as Childrens Advil, except in different dosages. Thus, it is not merely similar but rather identical. Thus, advertising/warning/lawsuit information about adult Advil should be discoverable. *See Jackson v. Firestone Tire & Rubber Co.,* 788 F.2d 1070 (5th Cir. 1986).

ii) Adult Advil is the same product.

Plaintiffs are not merely seeking information about a similar product, but seek information about the exact *same* product which is manufactured by this defendant. The main chemical component of Childrens Advil and adult versions is ibuprofen. As such, these products are all substantially similar, if not virtually identical.

Information about substantially similar or the same products is generally discoverable in product liability cases. In *Baine v. General Motors Corp.,* 141 F.R.D. 328 (M.D. Ala. 1991), a product liability design-defect case, the court makes the distinction that the plaintiffs were seeking information about the same product, not merely a similar product. *Baine*, 141 F.R.D. at 330. The court specifically states:

> *Here, we are not dealing with mere similarity, but rather, with virtual sameness.* A restraint system built upon the essential component of a pendulum-induced locking mechanism is at issue here. It is alleged that the locking mechanism failed. Therefore, all systems dependent upon a pendulum-induced locking mechanism have relevance to this litigation.

Id. at 330 (emphasis added).

F. <u>Defendants' position on lawsuits/notices of claims/labels involving adult Advil</u>

Plaintiffs' request for documents involving adult Advil, as opposed to Children's Advil, is supported neither by Plaintiffs' own discovery requests nor by the relevance standards of the Federal Rules.

Contrary to what they have now asserted, the bulk of Plaintiffs' original discovery requests only addressed *Children's* Advil, the drug allegedly ingested by LaBrea. Plaintiffs' requests sought information concerning "the drug,"[2] and they specifically defined "the drug "as *Children's* Advil. Here is their definition: "The drug is the nonsteroidal anti-inflammatory drug called Children's Advil, generic name ibuprofen, regardless of what trade name was used to refer to it, which plaintiffs allege caused the injury or damage complained of in this lawsuit." *See* Plaintiffs' Request for Production to Defendants-First Set at 2.

Now, Plaintiffs claim that "the drug" was intended to cover all forms of ibuprofen, regardless of the dosage or whether it was a prescription or over-the-counter formulation. To that end, they have tendered an affidavit from their hired expert to say, after-the-fact, that all packages containing ibuprofen are the "same drug." Plaintiffs' attempt to broaden the scope of the request should be rejected. First, the power to define their terms belonged exclusively to Plaintiffs. If they had intended a broader request, they should have more clearly asserted it. It is not fair to allow Plaintiffs to hide behind their own poorly-drafted definitions and then to claim "gotcha!". Second, Plaintiffs' current, broad interpretation of "the drug" is contradicted by their own discovery requests. When Plaintiffs elsewhere sought documents related to adult Advil, they specifically made a distinctive request. *See* Plaintiffs' Request for Production to Defendants-First Set at

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[2] Plaintiffs point to two discovery requests they erroneously claim to include adult Advil:

"**INTERROGATORY NO. 19:** If any notices of intent to file lawsuits, or actual lawsuits have been filed against the defendants for injury or death from use of ***the drug***, please state with regard to each lawsuit . . ." (emphasis added).

"**REQUEST NO. 26:** All petitions, complaints, or depositions in all lawsuits filed against you at any time regarding ***this drug***." (emphasis added).

Request No. 19 ("All warnings, instructions, labels, or package inserts ever distributed with ***adult Advil*** at any time."). According to well-recognized rules of construction, the fact that Plaintiffs knew how to ask for adult Advil when they wanted to should be taken to mean that their other requests were properly interpreted as applying only to Children's Advil.

Had Plaintiffs sought documents and information related to adult Advil in their requests, such discovery would be overly broad and not reasonably calculated to lead to the discovery of admissible evidence. First, adults are not the same as kids, and the difference shows up in the context of identifying likely causes of Stevens-Johnson Syndrome. For instance, one author first notes that "Drugs and malignancies most often are implicated as the [cause of SJS] in adults and the elderly," but then adds "Pediatric cases are related more often to infections than to malignancy or a reaction to a drug."[3] For that matter, *Plaintiffs' own document* (filed by one group in connection with a WHO inquiry) suggests that "age" is a critical variable in assessing the suitability of using a particular drug. Plaintiffs choose to ignore this distinction and simply assume that facts involving adult use will be probative of facts involving children's use. Second, Plaintiffs' requests are overbroad because they encompass lawsuits that have nothing to do with the symptoms alleged in this case. For instance, some users of Advil have contended that their prolonged use of the drug led to ulcers. However, even assuming that the existence of a link between adult Advil and gastrointestinal bleeding would be probative of a link between Children's Advil and gastrointestinal bleeding, the fact remains that this case has nothing to do with gastrointestinal bleeding. A lawsuit in which a person blames adult Advil for causing

[3] Steven Parrillo, DO, FACOEP, FACEP, *Stevens-Johnson Syndrome*, eMedicine (Nov. 26, 2002) (available at http://www.emedicine.com/emerg/topic555.htm).

gastrointestinal bleeding would not be probative in any way of the alleged link between Children's Advil and *Stevens-Johnson Syndrome* that is pertinent to this case.

G. <u>Plaintiffs' position on whether defendant is entitled to assert an objection/limitation on documents produced to those adverse events or injuries allegedly suffered by LaBrea Williams, or whether such objection has been waived:</u> (Interrogatory no. 18 & Req. Nos. 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, & 31: Requesting detailed information about all complaints of injury by the drug, and copies of all pre- or post-marketing Adverse Drug Experience Reports (ADEs), either during clinical trials or during the post-marketing period.).

These various requests seek the identification and production of ADEs and clinical trials data regarding *all* ADEs reported to be associated with Childrens Advil, both in electronic form, if available, or paper form. After initially tendering some of this data without objection, defendants are now attempting to limit it to ADEs dealing with adverse skin reactions. **(Att. 7-Ltr. from Bill Sims of 9/22).** It is plaintiffs' position that defendants should be required to produce *all ADE reports*, involving *all* adverse drug reactions, and identify by Bates stamp no., or answer this interrogatory in detail. Their objections should be overruled, for the following reasons:

i) Any objections to Req. Nos. 5, 8, 10, 12, 16, & 31 are clearly waived. Defendants did not timely object to any of the listed requests until Sims letter of Sept. 22, 2003, long after the thirty (30) day deadline provided by in the Rules.[4] *See* FED. R. CIV. P. 33(b)(3) (the party upon whom the interrogatories have been served shall serve a copy of the answers, and objections if any, within 30 days after the service of the interrogatories; *see also* FED. R. CIV. P. 34(b) (similar language as Rule 33). *See also Maloney v. Universalcom, Inc.,* 2001 U.S. Dist.

[4] Defendants' initial responses to this discovery were served on *June 10, 2003!* Thus, defendants mulled this over for more than three months before decided to make this objection. This is obvious evidence that it was not an oversight that was promptly corrected.

LEXIS 122, *2–4 (E.D. La. 2001) (objections to discovery were waived because they were not timely asserted); *cf., In re United States*, 864 F.2d 1153, 1154, 56 (5th Cir. 1989). This eleventh hour attempt is also a violation of agreements that were made in the face-to-face conference.

For example, in response to Req. No. 6, seeking all ADEs associated with the drug during all clinical trials, defendant responded *"All documents...responsive to this request are contained in the NDAs for Childrens Advil..(which will) be made available for inspection and copying at a mutually agreeable time and place.."* Similar responses were made to Requests 5, 8, 10, 12, 16, and 31. Thus, any objection to these requests at least has been waived.

Defendants seem to be arguing out of both sides of their mouth on this issue. They describe their failure to object on the one hand as a "moment of weakness," but on the other hand suggest that they failed to lodge "prophylactic objections" out of the goodness of their heart, implying a conscious decision. In reality, plaintiffs believe that what occurred was that they initially failed to object because, at first blush, the requests appeared to be relevant and reasonable. Indeed, as pointed out above, they did not make their objection to anything other than skin-related adverse events until Sims letter of Sept. 22, 2003, approximately three months after their initial responses were filed. Now, they have made a deliberate decision to obstruct discovery in this case in whatever manner possible.

This recent objection was obviously orchestrated by defense counsel Eric Stahl, who came into the case late, and decided for whatever reason with Mr. Sims' approval not only to rewrite all objections, but apparently to renege on several agreements that Sims made at the face-to-face settlement conference between lead counsel on Aug. 28. Whatever the reason for it, it is

clearly untimely, and there is no basis to allow a defendant to come in over three months after initial responses were filed and assert a whole set of new objections!

ii) All Adverse Drug Experience reports (ADEs) are clearly relevant and discoverable. Defendant did timely object to the other requests, mostly on the basis of relevancy, but their objection is without foundation. SJS is a syndrome with multiple symptoms, and is often misdiagnosed. The clinical and laboratory symptoms can include the following: Cutaneous: Confluent erythema, facial edema, skin pain, palpable purpura, skin necrosis, blisters or epidermal detachment, positive Nikolskys sign, mucous-membrane erosions, urticaria, swelling of the tongue; General: High fever, enlarged lymph nodes, arthralgia or arthritis, shortness of breath, wheezing, or hypotension. Lab results: eosinophil count elevated; lymphocytosis, abnormal liver function. Roujeau, et al, 331 *New Eng. J. Med.* 1272, 1274 (1994). ***(See also Att 4,* Affidavits of Dr. Rusty Nicar.).** Thus, reports of other symptoms, or even other diagnoses other than skin conditions as sought to be limited by defendant, are clearly relevant.

Nor are defendants' many arguments on the merits germane to this discovery dispute, one of which is that even if relevant, plaintiffs can not prove causation with ADE reports because they are anecdotal and not an accurate view of the universe of real complaints. This is obviously a substantive argument on the merits, and has nothing to do with discovery. Additionally, it is wrong. What defendants overlook is that you can compare the total ADEs between one drug and a comparable drug, and derive the *relative risk of SJS/TEN with a particular drug!*

Relative risk is defined as "the proportion of diseased people among those exposed to the relevant risk factor divided by the proportion of diseased people among those not exposed to the

risk factor." (Dictionary of Ecological Epidemiology). Therefore, if you have the total number of suspect skin reactions reported, and the total number of bottles of an OTC sold, you can obtain a relative risk of the reaction among takers of that drug compared with comparable drugs. A relative risk of greater than two is enough to prove causation in a toxic tort or pharmaceutical case. *Merrell Dow v. Havner,* 953 S.W2d 706, 716 (Tex. 1997). Of course, all of defendants' arguments on these points go to the merits, and not to the discoverability of the data sought, but it is clearly relevant.

Additionally, as shown by **Att. 4 (Nicar Supplemental Affidavit),** the FDA itself has stated in a 2003 Concept Paper, *Risk Assessment of Observational Data: Good Pharamacovigilance Practices and Pharmacoepidemiologic Assessment,* at p. 9 that

> ***"we believe that the calculation of reporting rates using spontaneously reported cases and estimates of patient exposure from prescription or patient level data may be a valuable step in the assessment of adverse events.*** *FDA recognizes the value of comparisons of reporting rates across similar or across different product classes prescribed for the same indication."* **(Att. 10, scientific articles relied on by plaintiffs.)** (emphasis added).

However, whether plaintiffs can or cannot prove their case on the merits with this evidence at this time is not the point. The key issue in this dispute is whether or not the information sought is relevant and discoverable. Relevant information does not even have to be admissible at trial so long as it appears ***reasonably calculated to lead to the discovery of admissible evidence.*** *FRCP* 26(b)(1); *Degen v. U.S.,* 517 U.S. 820, 825–26; 116 S.Ct. 1777, 1782 (1996).

Another point overlooked thus far in this dispute is that ***defendant has already admitted causation in previous package inserts***, so all of its cases holding that ADE data can't be used to

prove causation are inapposite. **(See, Att. 11, 1989 Children's Advil package insert).** There, almost 15 years ago, although it claims the incidence is less than 1%, ***defendant admitted a "probable causal relationship" between Children's Advil and SJS, but failed to include that warning on its box or bottle!*** Thus, all ADE data would be discoverable to assess the real risk of SJS, and plaintiffs would need *all* ADE data to make sure the real risk was not greater than 1%.

Additionally, most of the cases cited by defendants deal with Fed.R.Civ.Evid. 403, and the issue of *admissibility at trial.* For example, the defendants' cite *Haggerty v. Upjohn Co.,* 950 F. Supp. 1160 (S.D.Fla 1996), *aff'd* 158 F.3d 588 (11th Cir. 1998), for the proposition that ADE's are not discoverable because of their "unscientific nature." However, *Haggerty* dealt with the adequacy of proof at trial, not discovery! Likewise, they cite *Golod v. Hoffman LaRoche,* 964 F. Supp. 841 (S.D.N.Y. 1997), quoting the court as stating that ADE reports are not "sufficiently reliable or relevant to be admissible on the issue of causation." However, the complete quote by the court was as follows:

> While the reports may not be sufficiently reliable or relevant to be admissible on the issue of causation (citations omitted), they ***are relevant*** to Hoffman's awareness of potentially serious opthalmological effects and the possible need to conduct further research into them. *Id.* at 855 (emphasis added).

And defendants further miss the point about plaintiffs' contentions. They repeatedly argue that plaintiffs are attempting to obtain discovery about injuries "LaBrea Williams did NOT suffer"---which is false. What plaintiffs are seeking is *all* the injury data, to make sure that key skin reactions were not *miscoded as other systemic reactions when they were in fact skin reactions.* Without all adverse reaction data, it will be impossible for them to analyze this key issue. Defendants claim that all SJS cases would involve some skin problem. Once again, this

argument begs the question. Suppose that the problem is probably SJS (i.e., involves fever and stomatitis, or a mouth sore) but the drug is stopped by the treating clinician before a rash develops? This is a case that should properly be included in an analysis of SJS/TEN and related reactions, but does not involve a skin problem because the drug is timely stopped.

Additionally, the minor plaintiff in this case, LaBrea Williams, also suffered renal damage, as shown by **Att. 2 (Medical Records),** as well as pulmonary damage, damage to the mucosal layers of her esophagus, vagina, and anus. Her case demonstrates the multiple sequella suffered by victims of this disorder. Thus, in order to accurately assess whether or not all SJS and related reactions were properly reported to the FDA in the clinical trials in this case, plaintiffs must analyze them *all,* not just the ones the defendants claim are skin-related.

H. Defendants' position on whether documents related to adverse events not suffered by LaBrea Williams should be produced.

Discovery into injuries that LaBrea Williams did NOT suffer is not reasonably calculated to lead to the discovery of admissible evidence for *this case*, and Plaintiffs' insistence that Wyeth turn over its massive collection of information investigating and/or refuting potential linkages between Children's Advil and a wide range of injuries that have nothing to do with this case should be rejected.

1. Plaintiffs' waiver allegation

Not anticipating the current deluge, Wyeth originally responded to Plaintiffs' requests without lodging a series of prophylactic objections. Plaintiffs' counsel has now attempted to seize upon that moment of weakness by claiming that Wyeth has left the door open to its entire document vault without any recourse at all. However, the Federal Rules are not so wooden and

detached from practical concerns, especially where, as here, Plaintiffs have attempted to exploit its discovery requests to pry into a vast amount of documentation that has no probative value to this case at all. To head off Plaintiffs' ever-expanding discovery assault, the Court should practically limit the scope of Plaintiffs' requests to that information pertinent to the allegations in the Petition.

Under both Fed. R. Civ. P. 33 and 34, a Court has discretion to excuse a failure to make timely objections. *See* Fed. R. Civ. P. 33(b); *Richmark Corp. v. Timber Falling Consultants*, 959 F.2d 1468, 1473 (9th Cir. 1992). A district court has "broad discretion" to determine whether, and to what extent, to determine waiver. *Blumenthal v. Drudge*, 186 F.R.D. 236, 240 (D.D.C. 1999) ("[I]n the exercise of its broad discretion, the Court finds that plaintiffs have not waived their right to raise their objections even at this late date."); *see also* 8A WRIGHT & MILLER, FEDERAL PRACTICE AND PROCEDURE § 2176 (1994) (courts have "broad discretion" to determine whether discovery must be produced).

The factors most relevant to determining whether and to what extent a finding of waiver should be applied were spelled out by the court in *Drexel Heritage Furnishings v. Furniture USA*, which observed that "the Court should look into the circumstances behind the failure to object, whether it was inadvertent, defiant, or part of a larger calculated strategy of noncompliance." 200 F.R.D. 255, 259 (M.D.N.C. 2001). The Court in *Drexel* also suggested "look[ing] at subsequent actions by the party to ascertain whether it was acting in good faith, as opposed to acting in a disinterested, obstructionist, or bad faith manner. The Court should always take into account any resulting prejudice or lack thereof, and the need to preserve the

integrity of the rules by serving as a warning to other litigations. Finally, the Court may assess lesser sanctions that may be more appropriate." *Id.*

Applying these factors to the present case, the Court should not find that Wyeth has waived its objections to Plaintiffs' excessive discovery requests. First, there is no suggestion that Wyeth was acting either "defiantly" or as part of a calculated strategy of "noncompliance." To the contrary, Wyeth has agreed to provide to Plaintiffs all of its materials that shed light on the claims asserted in this case – whether LaBrea Williams' ingestion of Children's Advil caused her Stevens-Johnson Syndrome and whether Wyeth should have included additional or different warnings to alert potential users to the potential relationship between the drug and the disease. Second, the record indicates that Wyeth has a good faith basis for resisting the production of the requested documents. Third, because of the lack of relevance of the documents to *this* case, Plaintiffs cannot claim prejudice from Wyeth's request. Like the court in *Drexel*, this Court should find that Wyeth's failure "was not egregious because there has not been a history of delay or other bad faith" and the delay in lodging the objection has not "substantially hindered or delayed" Plaintiffs' pursuit of this case. *Drexel*, 200 F.R.D. at 259.

2. *Plaintiffs' assertion that all adverse event reports are relevant is unsupportable.*

As a fallback argument, Plaintiffs argue that even reports concerning the injuries that LaBrea Williams did not suffer are still relevant. These arguments miss their mark.

a. Even if someone who contracted Stevens-Johnson Syndrome had been misdiagnosed, a report involving some dermatological diagnosis would still be filed and the report would, therefore, be produced by Wyeth.

Plaintiffs first allege that Stevens-Johnson Syndrome is often "misdiagnosed" and suggest that they, therefore, need access to ***all*** adverse event reports so that they can look for unrecognized cases of Stevens-Johnson Syndrome. This argument ignores that Wyeth is not only producing those reports which are officially categorized as "Stevens-Johnson Syndrome," but are also producing ***any*** report of any dermatological affliction (and, for that matter, reports concerning certain non-skin conditions that Plaintiffs had identified). Wyeth's agreement to provide all skin-related reports without regard to whether a specific diagnosis of "Stevens-Johnson Syndrome" is made fully addresses any viable "misdiagnosis" concern. Boccuti Affid. ¶¶ 5-6 (**Att. 8**).

Stevens-Johnson Syndrome is an extremely rare skin disorder that invariably includes distinct and highly visible dermatological features. Indeed, its clinical classification is "based on the pattern of 'EM-like lesions' . . . and on the extent of epidermal detachment." Specifically, Stevens-Johnson Syndrome involves not only epidermal ***detachment*** of up to 10% of the body surface area, but also "widespread erythematous or purpuric macules or flat atypical targets." Abstract: JC Roujeau, 102(6) J. OF INVESTIG. DERMATOL. 28S (1994) (copies of the medical literature cited herein by Defendants are attached as **Attachment 9**). In the face of these palpable features, if Stevens-Johnson Syndrome is ever misdiagnosed, it is because the diagnosing physician mistakenly believes that the patient suffers from some other ***skin*** condition. *See, e.g.*, Abstract: N. Bachot et al., *Differential Diagnosis of Severe Cutaneous Drug Eruptions*, 4(8) AM. J. CLIN. DERMATOL. 561 (2003) (noting various skin disorders which are potential misdiagnoses). There is no suggestion by anyone that a person can be afflicted with Stevens-Johnson Syndrome yet have no dermatological symptoms.

Because of the nature of Stevens-Johnson Syndrome, Wyeth will code cases involving such dermatological features under the "skin/subcutaneous disorders" organ system (either as the primary characterization or as a secondary characterization). Roujeau, *supra*; Boccuti Aff. ¶¶ 5-6. In turn, by agreeing to produce all reported dermatological events, Wyeth has ensured that all potential Stevens-Johnson Syndrome events will be reported, even if the reports do not specifically reference "Stevens-Johnson Syndrome."

b. Plaintiffs are not entitled to put Children's Advil on trial by dragging out all afflictions (of whatever nature) ever allegedly suffered by individual users.

Plaintiffs have also suggested that reports of non-dermatological adverse events are relevant to their effort to challenge the overall safety of Children's Advil. Plaintiffs hope to put the entire drug, Children's Advil, on trial, and these discovery requests are part and parcel of that effort. *See* Nicar Aff. ¶ 4 (hoping to review entire databases of data in order to evaluate overall "efficacy and safety of Children's Advil"). As other courts have recognized, this is an excessive strategy, designed mainly to prejudice juries, which lacks probative value. *See Coursen v. A.H. Robins Co.*, 764 F.2d 1329, 1334 (9th Cir. 1985) (in Dalkon Shield case, evidence "related to side effects other than pelvic inflammatory disease," the injury alleged by the plaintiffs, was properly excluded under Federal Rule of Evidence 403 because "it does nothing except generally show defendant in a bad light") (quoting trial court's ruling); *see also O'Banion v. Owens-Corning Fiberglass Corp.*, 968 F.2d 1011, 1012-13 (10th Cir. 1992) (affirming, "due to lack of relevance," a ban on any mention of the word "cancer" or the presentation of any evidence relating to cancer in non-cancer asbestos cases); *In re Related Asbestos Cases*, 543 F. Supp. 1152, 1160 (N.D. Cal. 1982) (excluding in asbestos litigation any reference to cancer "[i]n any

cases in which the plaintiff has not contracted cancer"); *In re Norplant Contraceptive Prods. Liab. Litig.*, 1997 WL 81094, at *1 (E.D. Tex. Feb. 21, 1997) (stating, after excluding evidence of the inadequacy of warnings of side effects not alleged by plaintiffs as irrelevant, that "even if relevant, the court finds that any probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, and misleading the jury"). Plaintiffs' incentive to pursue such a strategy is especially great in a case such as this, where the incidence of Stevens-Johnson Syndrome is so rare that the likelihood of a jury finding fault with Wyeth would be negligible (if it would exist at all) unless Plaintiffs can succeed in shifting the jury's focus to more common adverse events.

Thus, Plaintiffs' expert suggests that he hopes to re-assess the entirety of the FDA's decision to approve Children's Advil. *See* Nicar Aff. ¶ 5 (expert compares his role in this litigation to FDA's role in approving Children's Advil). However, the pertinent questions in this case should be limited to whether Children's Advil caused LaBrea Williams to suffer Stevens-Johnson Syndrome and whether Wyeth should have included an additional warning beyond the warning already provided concerning possible adverse dermatological reactions. The broad-based attack on Children's Advil and the discovery sought to support that attack are excessive and unreasonable.

c. Plaintiffs' request for non-dermatological ADEs is especially unwarranted because such documents cannot be used to establish either causation or rate of incidence.

Assuming for a moment that Plaintiffs were entitled to put Children's Advil on trial (which they are not), the request for non-dermatological ADEs would still be unwarranted inasmuch as the ADEs are not probative for the purpose that Plaintiffs' expert says he would use

them, i.e., to show a causal relationship between a drug and a symptom or to show the incidence of such symptoms. *See* Nicar Aff. ¶ 9.[5]

Plaintiffs simply assume that ADEs would be probative of potential causal links between Children's Advil and various adverse events. However, because of their unscientific nature, ADEs cannot be used in this way. The same flaw which undercuts Plaintiffs' reasoning was discussed in *Haggerty v. Upjohn Co.*, 950 F. Supp. 1160 (S.D. Fla. 1996), *aff'd* 158 F.3d 588 (11th Cir. 1998). There the court noted that the ADE reports sent to the FDA "contain raw information that has not been scientifically or otherwise verified as to cause and effect." *Id.* at 1164. The "primary purpose of the SRS [Spontaneous Reporting System] is to serve as a signaling system for adverse drug reactions that may not have been detected during pre-market testing; however, according to the FDA, there is no certainty that the suspect drug caused the reaction." *Id.*[6] The *Haggerty* court also recognized that the "FDA has confirmed that the SRS

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[5] ADEs have no utility in this litigation, except perhaps to show that Wyeth had "notice" of a possible causal relationship. But the only issue where "notice" is relevant in this case is with respect to the specific symptoms alleged by LaBrea Williams insofar as Wyeth's awareness of those symptoms may relate to Plaintiffs' "failure to warn" claim. Because Wyeth has already agreed to provide the ADEs which would be relevant for that purpose, there is no supportable justification for demanding additional ADEs.

[6] This is because of the nature of the ADE reporting system. The FDA defines an adverse drug experience as one "temporally associated with use of the product, ***whether or not considered drug related*** . . . ." 21 C.F.R. § 314.80(a) (1999) (emphasis added). The FDA has stated that:

> For any given report, there is no certainty that the suspect drug caused the reaction. This is because physicians and all reporters are encouraged to report all suspected adverse drug events, not just those that are known to have been caused by the product. The event may have been related to an underlying disease for which the drug or biologic was given, to other drugs or biologics being taken concurrently, or may have occurred by chance at the same time the suspected drug was taken . . . .

Alan Gelberg & George D. Armstrong, *A Study of the Utilization of the FDA's Adverse Drug*

information ***cannot be used to estimate the incidents of adverse drug reactions, or for comparisons of drug safety***." *Id.* (emphasis added). The court concluded that the "SRS reports . . . cannot be used to arrive at a cause and effect conclusion." *Id.* Accordingly, the court precluded any reliance upon ADEs as proof of causation and as a basis for an expert opinion as to causation. *Id.*

For these same reasons, other courts have likewise analyzed ADEs and have rejected them when offered as proof of causation or as a means to quantify risks. *See, e.g., Saari v. Merck & Co.*, 961 F. Supp. 387, 397-98 (N.D.N.Y. 1997) (explaining that doctors' reports to the FDA Med Watch program was "neither confirming nor denying that there is any relationship between her symptoms and the vaccine," and holding that it is "readily apparent" that a summary report of vaccine ADEs is "not admissible and/or not probative on the issue of causation"); *Golod v. Hoffman LaRoche*, 964 F. Supp. 841, 855 (S.D.N.Y. 1997) (ADE reports are not "sufficiently reliable or relevant to be admissible on the issue of causation"); *Wade-Greaux v. Whitehall Labs., Inc.*, 874 F. Supp. 1441, 1483 (D.V.I. 1994) (drug event reports "have inherent biases that make them unreliable. As a result, such anecdotal human data do not represent the type of data reasonably relied upon by experts in the field . . . ."), *aff'd*, 46 F.3d 1120 (3d Cir. 1994); *DeLuca v. Merrell Dow Pharms.*, 791 F. Supp. 1042, 1050 (D.N.J. 1992) (holding that ADEs "are not of a type of data that are reasonably relied upon by experts in the fields of epidemiology and public health to make a determination of the causal relationship between a given substance and human birth defects" and noting that even the plaintiff's expert admitted that ADEs "are anecdotal reports which cannot alone be used to prove causation"), *aff'd*, 6 F.3d 778 (3d Cir. 1993); *Jacobs*

Reaction Database, 24 DRUG INFO. J. 785, 786 (1990) (analyzing the Adverse Reactions

v. Dista Prods. Co., 693 F. Supp. 1029, 1034 (D. Wyo. 1988) ("[R]aw information which has not all been scientifically or otherwise verified . . . cannot be used to estimate the incidence of adverse drug reactions.").

The FDA itself acknowledges that ADEs are not indicative of whether the drug caused the adverse event: "A report or information submitted by an applicant under this section (and any release by FDA of that report or information) does not necessarily reflect a conclusion by the applicant or FDA that the report or information constitutes an admission that the drug caused or contributed to an adverse effect." 21 C.F.R. § 314.80(k) (1999). Further, "[a]n FDA report has concluded that 'ADR [ADE] reports have in fact not been useful beyond a role as stimulators of interest.'" *DeLuca*, 791 F. Supp. at 1051.

Plaintiffs can offer no other reason for why they want these ADEs other than to try to establish that Children's Advil is unsafe on the grounds that it *causes* these adverse events. But, because the entire premise underlying Plaintiffs' requests for non-dermatological ADEs is mistaken, those requests should be rejected.

Wyeth requests that the Court rein in Plaintiffs' attempts to exploit the discovery process and that it limit or reject outright Plaintiffs' excessive discovery requests.

Reporting System of the FDA Division of Epidemiology and Surveillance).

Dated this 10 day of November, 2003.

Respectfully submitted,

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